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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/605,825	10/29/2003	James C. Kennedy	67286-277	2824

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EXAMINER	
SHARAREH, SHAHNAM J	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/605,825	KENNEDY ET AL.	
	Examiner	Art Unit	
	Shahnam Sharareh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *1-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/26/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse of Group II and the species directed to 5-ALA in the reply filed on January 21, 2005 is acknowledged. The traversal is on the ground(s) that no undue burden of search has been established and that the classification is not a proper basis of establishing different field of search. This is not found persuasive because for the purposes of the initial requirement a serious burden on the examiner may be *prima facia* shown if the examiner shows appropriate explanation of separate classification or status in the art (see MPEP §§ 803.01 or 808.02).

Applicant has also argued that classification of the Group I in class 424, subclass 9.6 is incorrect because such class is directed to diagnostic or test agents. (see Arguments at page 2). In response Examiner replies that the instant claims 3-4 are directed to methods of detecting a skin lesion, which is construed as a diagnostic methodology. Thus, Applicant's arguments are not persuasive.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on January 21, 2005.

This application contains claims 1-14 drawn to an invention nonelected with traverse. A complete reply to the ~~final~~ rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15-19, 21-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of treating malignant skin lesions with 5-aminolevulinic acid (5-ALA), does not reasonably provide enablement for methods of treating any malignant skin lesions including for example Sacromas secondary to an HIV infection with any agent which is not in itself a photosenitizer but which induces accumulation of protoporphyrin IX in a cellular target. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. However, these factors are illustrative, not mandatory and what is relevant depends on the specific facts. All of these factors need not be reviewed when determining whether a disclosure is enabling. *Id.* When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:

The invention provides for methods of treating any malignant skin lesions on patient body with any agent which is not in itself a photosensitizer but which induces accumulation of protoporphyrin IX in a cellular target by photoactivating the protoporphyrin IX.

(2) The state of the prior art

The state of art is directed to methods of photodynamically treating infections and non-malignant hyperproliferative skin diseases with 5-ALA, benzoprotoporphyrins or derivatives thereof.

(3) The relative skill of those in the art

The relative skill of those in the art is high and encompass anyone with understanding of clinical radiology.

(4) The predictability or unpredictability of the art

The unpredictability of the clinical medicine is very high. The art at the time of invention was essentially directed to methods of administering photodynamic therapy by administering effective amounts of a photosensitizing agent. Aside from 5-ALA, the use of agents that are not photosensitizer, but induce accumulation of protoporphyrin IX in a cellular target was not well described. In fact, there is no predictability that protoporphyrins IX synthesis is induced in the target cells. Accordingly, there is not predictability in the art and apprising the entire scope of the instant claims requires pain staking experimental study.

(5) The breadth of the claims

The claims are very broad. The claims are directed to methods of treating any malignant skin condition by administering an agent which is not in itself a photosensitizer but which induces accumulation of protoporphyrin IX in a cellular target. The scope of applicable agents that can provide the claimed function is unknown. Further, their utility in treating all types of malignant skin lesions, their reach to deep layered tissues, their affect on the underlying condition, etc.. are not described.

Further, the instant claims appear to place a function at the point of novelty of the instant methodology. Attention is directed to *General Electric Company v. Wabash Appliance Corporation et al* 37 USPQ 466 (US 1938), at 469, speaking to functional language at the point of novelty as herein employed: "the vice of a functional claim exists not only when a claims is "wholly" functional, if that is ever true, but when the inventor is painstaking when he recites what has already been seen, and then uses conveniently functional language at the exact point of novelty". Functional language at the point of novelty, as herein employed by Applicants, is further admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC 1997) at 1406: stating this usage does "little more than outlin[e] goals appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate".

As it has repeatedly been stressed by the Courts, an assay for determining whether a given compound possesses certain desired characteristics and identifies some broad categories of compound that might work, these descriptions, without more precise guidelines, amount to little more that "a starting point, a direction for further research." See *Genetech v. Novo Nordisk A/S,* 108 F.3d 1361,1366,(Fed. Cir.), also *Enzo Biochem, Inc. V. Calgene*, Inc, 1888 F.3d 1362, 1374 (Fed. Cir. 1999).

Here, Applicants functional language at the point of novelty fails to meet the requirements set forth under 35 USC 112, first paragraph, because it does not with reasonable degree of certainty elaborate on the scope of the instant claims. Claims employing functional language at the point of novelty, such as Applicants', neither

provide those elements required to practice the inventions, nor "inform the public during the life of the patent of the limits of the monopoly asserted"

(6) The amount of direction or guidance presented

The instant claims merely calls for the use of a trial and error to attempt to find a agents that will improve treatment of fungal infections. The instant specification first fails to identify potential useful agents or their mechanism of action for screening. Even though the specification may provide for an exemplary drug from the group of such compounds as 5-ALA, it does not provide necessary link between finding a particular compound and narrowing the range of candidates in order to find a suitable compound without the need for undue experimentation. Given the broad breadth of the claims the ordinary skill in the art would not have any guidance as what type of compounds should he proceed with.

Further, it is not clear which type of patients are in need of the claimed therapy. Are all patients who receive a dose of photochemotherapy are subject to the end clinical point of the instant claims?

(7) The presence or absence of working examples

The specification merely provides examples directed to the use of 5-ALA. There are no other types of compounds described for the intended benefits. In fact, there is no evidence provided in the specification showing that all possible nonphotosensitzers do in fact cause accumulation of protopohyrin IX in the cellular target of interest.

Moreover, the instant specification is merely directed to methods of treating fungal infection. Only, patients suffering from basal cell skin squamous or carcinomas have been suggested to benefit with the instantly claimed methodologies.

(8) The quantity of experimentation necessary

Since the significance of agents which are not in itself a photosenistzer, but which induced accumulation of protoporphyring IX in a cellular target and their biological activity cannot be predicted a priori but must be determined from the case to case by painstaking experimental study and when the above factors are weighed together, one of ordinary skill in the art would be burdened with undue "painstaking experimentation study" to determine the all of the possible disease states or all the agents suitable for the intended benefits. Thus, practicing the entire scope of the instant claims require undue experimentation.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225

USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 15-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-2 of US Patent 5,211,938; claims 1-7 or US Patent 5,079,262; claims Although the conflicting claims are not identical, they are not patentably distinct from each other because they overlap in scope.

Each set of the patented claims are directed to methods of treating malignant skin conditions using 5-ALA and photodynamic therapy. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to practice the scope of the instant claims by employing the patented claims.

Claims 15-25 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of copending Application No. 10/663,992; claims 1-20 of copending application, 10605,826; claims 1-19 of copending application 09/928,505 and the claims 1-15 of copending application 09/816,329 Although the conflicting claims are not identical, they are not patentably distinct from each other because each of set of the copending applications are also directed methods of treating malignant skin lesions with 5-ALA. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of

invention to practice the scope of the instant claims once in possession of the copending claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 15-19, 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pandey et al US Patent 5,093,349

Pandey teaches methods of treating skin tumors comprising topically administering to a patient dimers of deuteroporphyrins or hydrophobic esters thereof which are derivatives of protoporphyrin-IX. (see abstract) Pandey further administers light to the site of interest. (see col 10-11, specifically col 11, lines 1, 32-39). Pandey's compounds are hexy ethers of a tetrapyrole. There is no indication that such

compounds are photosensitive themselves outside a body. Further, since such compounds are hydrolyzed to protoporphyrin, they are viewed to induce the synthesis of such compound in vivo.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to practice the scope of the instant claims by Pandey's methodologies, because as taught by Pandey, other esters or dimers of protoporphyrin are suitable for treating skin tumor lesions such as carcinomas.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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SREENI PADMANABHAN
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